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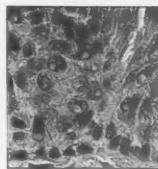
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TORADOL® and TORADOL® ORAL
(ketorolac tromethamine)

maximum milk concentration observed was 7.3 ng/mL and the maximum milk-to-plasma ratio was 0.037. After one day of dosing (qid), the maximum milk concentration was 7.9 ng/mL and the maximum milk-to-plasma ratio was 0.025. Caution should be exercised when TORADOL® is administered to a nursing woman.

Pediatric Use

Safety and efficacy in children have not been established. Therefore, TORADOL® is not recommended for use in children.

Use in the Elderly

Because ketorolac tromethamine is cleared somewhat more slowly by the elderly (see CLINICAL PHARMACOLOGY section of full prescribing information) who are also more sensitive to the renal effects of NSAIDs (see PRECAUTIONS — Renal Effects), extra caution and reduced dosages (see DOSAGE AND ADMINISTRATION section of full prescribing information) should be used when treating the elderly with TORADOL®.

ADVERSE REACTIONS

Adverse reaction rates from short-term use of NSAIDs are generally from 1/10 to 1/2 the rates associated with long-term use. This is also true for TORADOL. Adverse reaction rates also may increase with higher doses of TORADOL (see WARNINGS, and DOSAGE AND ADMINISTRATION section of full prescribing information). TORADOL® is indicated for short-term use. Physicians using TORADOL should be alert for the usual complications of NSAID treatment, and should be aware that with longer use (exceeding 5 days) of TORADOL, the frequency and severity of adverse reactions may increase. Physicians using TORADOL should be alert to the relative risks associated with dose and dose duration as described in CLINICAL PHARMACOLOGY — Clinical Studies section of full prescribing information. Physicians using TORADOL should be alert for the usual complications of NSAID treatment. The adverse reactions listed below were reported in clinical trials with TORADOL in which patients received up to 20 doses, in 5 days, of TORADOL 30 mg or up to 4 doses a day from long-term studies of TORADOL® 10 mg qid. In addition, adverse reactions that were reported from TORADOL postmarketing surveillance are included in "Incidence 1% or Less." **Incidence Greater than 1%** (probably causally related): **Body as a Whole:** EDEMA; **Cardiovascular:** HYPERTENSION; **Dermatologic:** RASH, pruritus; **Gastrointestinal:** NAUSEA (12%), DYSPERSEASIA (12%), GASTROTESTINAL PAIN (13%), constipation, diarrhea*, flatulence, gastrointestinal fullness, vomiting, STOMATITIS; **Hemic and Lymphatic:** purpura; **Nervous System:** drowsiness*, dizziness*, HEADACHE (17%), sweating. Injection site pain was reported by 2% of patients in multidose studies (vs. 5% for the morphine control group). "Incidence of reported reaction between 3% and 9%. Those reactions occurring in less than 3% of the patients are unmarked. Reactions reported predominantly from long-term TORADOL® studies are CAPITALIZED. **Incidence 1% or Less** (probably causally related): **Body as a Whole:** hypersensitivity reactions such as anaphylaxis*, bronchospasm, laryngeal edema, tongue edema, hypotension, and flushing, weight gain, fever; **Cardiovascular:** flushing, palpitation, pallor, hypertension, syncope; **Dermatologic:** Lyell's syndrome, Stevens-Johnson syndrome, exfoliative dermatitis, maculo-papular rash, urticaria; **Gastrointestinal:** peptic ulceration, GI hemorrhage, GI perforation (see WARNINGS and PRECAUTIONS), melena, rectal bleeding, gastritis, eructation, anorexia, increased appetite; **Hemic and Lymphatic:** postoperative wound hemorrhage, rarely requiring blood transfusion (see WARNINGS and PRECAUTIONS); thrombocytopenia, epistaxis, anemia; **Nervous System:** convulsions, vertigo, tremors, abnormal dreams, hallucinations, euphoria; **Respiratory:** dyspnea, asthma, pulmonary edema; **Urogenital:** acute renal failure (see WARNINGS and PRECAUTIONS), flank pain with or without hematuria and/or azotemia, oliguria, nephritis.

*Italics denote reactions reported from postmarketing experience. **Other Adverse Events** (causal relationship unknown): **Body as a Whole:** asthenia; **Gastrointestinal:** pancreatitis; **Hemic and Lymphatic:** leukopenia; EOSINOPHILIA; **Nervous System:** paresthesia, depression, insomnia, nervousness, excessive thirst, dry mouth, abnormal thinking, inability to concentrate, hyperkinetics, stupor; **Respiratory:** RHINITIS, COUGH, dyspnea; **Special Senses:** abnormal taste, abnormal vision, blurred vision, tinnitus, HEARING LOSS; **Urogenital:** polyuria, increased urinary frequency.

2Reactions occurred under circumstances where the causal relationship to TORADOL treatment has not been clearly established; they are presented as alerting information for physicians. Reactions reported predominantly from long-term TORADOL® studies are CAPITALIZED.

See package insert for full prescribing information.

CAUTION: Federal law prohibits dispensing without prescription.

U.S. Patent No. 4,089,969 and others



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Palo Alto, CA 94304
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Zantac® 150 Tablets
(ranitidine hydrochloride)

Zantac® 300 Tablets
(ranitidine hydrochloride)

Zantac® Syrup
(ranitidine hydrochloride)

The following is a brief summary only. Before prescribing, see complete prescribing information in Zantac® product labeling.

INDICATIONS AND USAGE: Zantac® is indicated in:

1. Short-term treatment of active duodenal ulcer. Most patients heal within 4 weeks.

2. Maintenance therapy for duodenal ulcer patients at reduced dosage after healing of acute ulcers.

3. The treatment of pathological hypersecretory conditions (e.g., Zollinger-Ellison syndrome and systemic mastocytosis).

4. Short-term treatment of active, benign gastric ulcer. Most patients heal within 6 weeks and the usefulness of further therapy has not been demonstrated.

5. Treatment of gastroesophageal reflux disease (GERD). Symptomatic relief commonly occurs within 1 or 2 weeks after starting therapy with Zantac 150 mg b.i.d.

6. Treatment of endoscopically diagnosed erosive esophagitis. Healing of endoscopically diagnosed erosive esophagitis occurs at 4 weeks (47%), 8 weeks (71%), and 12 weeks (84%) of therapy with Zantac 150 mg o.d.

Symptomatic relief of heartburn commonly occurs within 24 hours of therapy initiation with Zantac.

Concomitant antacids should be given as needed for pain relief to patients with active duodenal ulcer; active, benign gastric ulcer; hypersecretory states; GERD; and erosive esophagitis.

CONTRAINdications: Zantac® is contraindicated for patients known to have hypersensitivity to the drug.

PRESCRIBING INFORMATION: Symptomatic response to Zantac® therapy does not preclude the presence of gastric malignancy. Since Zantac is excreted primarily by the kidney, dosage should be adjusted in patients with impaired renal function (see DOSAGE AND ADMINISTRATION). Caution should be observed in patients with hepatic dysfunction since Zantac is metabolized in the liver.

Laboratory Tests: False-positive tests for urine protein with Multistix® may occur during Zantac therapy, and therefore testing with sulfosalicylic acid is recommended.

Drug Interactions: Although recommended doses of Zantac do not inhibit the action of cytochrome P-450 enzymes in the liver, there have been isolated reports of drug interactions that suggest that Zantac may affect the bioavailability of certain drugs by some mechanism as yet unidentified (e.g., a pH-dependent effect on absorption or a change in volume of distribution).

Incidence of increased prothrombin times have been reported during concurrent use of ranitidine and warfarin. However, these pharmacokinetic studies with dosages of ranitidine up to 400 mg per day, no interaction occurred; ranitidine had no effect on warfarin clearance or prothrombin time. The possibility of an interaction with warfarin at dosages of ranitidine higher than 400 mg per day has not been investigated.

Precautions, Adverse Reactions, Pregnancy Category B: Reproduction studies have been performed in rats and rabbits at doses up to 160 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Zantac. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: Zantac is secreted in human milk. Caution should be exercised when Zantac is administered to a nursing mother.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: Headache, sometimes severe, seems to be related to Zantac® administration. Constipation, diarrhea, nausea/vomiting, abdominal discomfort/pain, and, rarely, pancreatitis have been reported. There have been rare reports of malaise, dizziness, tachycardia, insomnia, vertigo, tinnitus, hypertension, hypotension, bradycardia, ventricular beats, and arrhythmias. Rare cases of reversible mental confusion, depression, and hallucinations have been reported, predominantly in severely elderly patients. Rare cases of reversible blurred vision suggestive of a change in accommodation have been reported. Rare reports of reversible involuntary motor disturbances have been received.

In normal volunteers, SGPT values were increased to at least twice the baseline value in 12 subjects receiving 100 mg of Zantac orally intravenously for 7 days, and in 4 of 24 subjects receiving 50 mg i.v. infrequently for 5 days. There have been occasional reports of hepatitis, hepatocellular or hepatocanicular or mixed, with or without jaundice. In such circumstances, ranitidine should be immediately discontinued. These events are usually reversible, but in exceedingly rare circumstances death has occurred.

Blood count changes (leukopenia, neutropenia, thrombocytopenia, and thrombocytosis) have been reported in a few patients. These were usually reversible and in most patients resolved when Zantac was discontinued. It is also a case of agranulocytosis, pancytopenia, sometimes with marrow hypoplasia, and aplastic anemia and exceedingly rare cases of acquired immune hemolytic anemia have been reported.

Although controlled studies have shown no antidiuretic activity, occasional cases of gynecomastia, impotence, and loss of libido have been reported in male patients taking Zantac, but the incidence did not differ from that in the general population.

Incidents of rash, including rare cases suggestive of mild erythema multiforme, and rarely, alopecia, have been reported, as well as rare cases of hypersensitivity reactions (e.g., bronchospasm, fever, rash, eosinophilia), anaphylaxis, angioneurotic edema, and small increases in serum creatinine.

OVERDOSAGE: Information concerning possible overdosage and its treatment appears in the full prescribing information.

DOSAGE AND ADMINISTRATION: (See complete prescribing information in Zantac® product labeling.)

Initial Dose: Patients With Impaired Renal Function: On the basis of experience with a group of subjects with severely impaired renal function treated with Zantac, the recommended dosage in patients with a creatinine clearance less than 50 mL per minute is 150 mg or 10 mL (2 teaspooons equivalent to 150 mg of ranitidine) every 24 hours. Should the patient's condition require, the frequency of dosing may be increased to 12 hours or even further with caution. Hemodialysis reduces the level of circulating ranitidine. The dosing schedule should be adjusted so that the timing of a scheduled dialysis session will coincide with the next dose.

HOW SUPPLIED: Zantac® 150 Tablets (ranitidine HCl equivalent to 150 mg of ranitidine) are peach, film-coated, five-sided tablets embossed with "ZANTAC 150" on one side and "Glanz" on the other. They are available in bottles of 60 (NDC 0173-0344-42) and 100 (NDC 0173-0344-09) tablets and unit dose packs of 100 (NDC 0173-0344-47) tablets.

Zantac® 300 Tablets (ranitidine HCl equivalent to 300 mg of ranitidine) are yellow, film-coated, five-sided tablets embossed with "ZANTAC 300" on one side and "Glanz" on the other. They are available in bottles of 30 (NDC 0173-0393-40) tablets and unit dose packs of 100 (NDC 0173-0393-47) tablets.

Store between 15° and 30°C (68° and 86°F) in a dry place. Protect from light. Replace cap securely after each opening.

Zantac® Syrup, a clear, peppermint-flavored liquid, contains 16.8 mg of ranitidine HCl equivalent to 15 mg of ranitidine per 1 mL in bottles of 16 fluid ounces (one liter) (NDC 0173-0344-48).

Store between 4° and 25°C (39° and 77°F). Dispense in light-resistant containers as defined in the USP-NF.

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92 Apr 135. Bullous myringitis, tophi of gout, polychlorinated biphenyl dermatitis, acral fibrokeratoma, plant contact dermatitis, leukoplakia of the tongue.

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92 Jun 127. Tinea incognito, ulcerating basal cell carcinoma, exfoliative erythroderma, Bell's palsy, myotonic dystrophy, rickets in young child.

92 Jul 125. Allergic angioedema, bullous pemphigoid, granuloma pyogenicum, contact sensitization following herpes zoster, iliac artery aneurysm, cutaneous horn.

92 Aug 94. Goiter in postpartum thyroiditis, dermatitis from old sandal, Ehlers-Danlos syndrome,

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May 1992
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Zantac® 150 Tablets/Zantac® 300 Tablets:
Glaxo Pharmaceuticals, Research Triangle Park, NC 27709

Zantac® Syrup:
Manufactured for Glaxo Pharmaceuticals, Research Triangle Park, NC 27709
by Roxane Laboratories, Inc., Columbus, OH 43216

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